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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/591,340

08/31/2006

Kai Rossen

7601/88254

9531

66991

7590

04/21/2008

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EXAMINER

LOEWE, SUN JAE Y

ART UNIT

PAPER NUMBER

1626

MAIL DATE

DELIVERY MODE

04/21/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/591,340	<b>Applicant(s)</b> ROSSEN ET AL.	
	<b>Examiner</b> SUN JAE Y. LOEWE	<b>Art Unit</b> 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 5-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2-9-2007</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Claims 5-24 are pending in the instant application. Claims 1-4 were cancelled by preliminary amendment filed on August 31, 2006.

#### ***Election/Restrictions***

2. Applicant's election without traverse of species wherein X=-COOH and PG=tert-butoxycarbonyl in the reply filed on February 28, 2008 is acknowledged.

3. MPEP § 803.02 provides the following guideline:

“Markush-type claim will be examined fully with respect to the elected species and further to the extent necessary to determine patentability. If the Markush-type claim is not allowable \*\*, the provisional election will be given effect and examination will be limited to the Markush-type claim and claims to the elected species, with claims drawn to species patentably distinct from the elected species held withdrawn from further consideration.

If on examination the elected species is found to be anticipated or rendered obvious by prior art, the Markush-type claim and claims to the elected species shall be rejected, and claims to the nonelected species would be held withdrawn from further consideration.”

The elected species was not allowable (see Section 7). Furthermore, the Markush-type claim was also not allowable (see Section 6). Thus, the provisional election was given effect and non-elected species were withdrawn from further consideration. The non-elected species are: claimed processes that result in the preparation of compounds of Formula I wherein X ≠ -COOH and PG ≠ tert-butoxycarbonyl.

***Priority***

4. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

***Information Disclosure Statement***

5. The information disclosure statement (IDS) submitted on February 9, 2007 was in compliance with the provisions of 37 CFR 1.97 and 37 CFR 1.98. The IDS was considered. A signed copy of form 1449 enclosed herewith.

***Claim Objections***

5. Claims 5-24 objected to for containing non-elected subject matter.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 5-24 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is drawn to “derivatives of the general formula (I).” The terms “derivatives” and “general” render the claim indefinite because the metes and bounds cannot be ascertained. The term "derivative" has an art recognized definition of “compounds obtained from another compound by a simple chemical process or an organic compound containing a structural radical similar to that from which it is derived” (Hackh's chemical dictionary, 1972). The term

“general” is recognized to mean “involving, relating to, or applicable to every member of a class” (Merriam-Webster Online Dictionary). Thus, it is not clear whether the claims are limited to compounds that fit the definition of Formula I, or whether the claims encompass a broader range of compounds not defined by the Markush-type formula.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

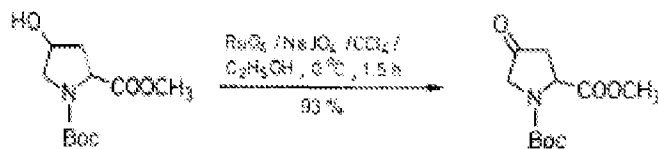
The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
7. Claims 5-24 rejected under 35 U.S.C. 103(a) as being unpatentable over Dormoy et al. in view of Carlsen et al. and Riley et al., further in view of Narukawa et al.

#### *Determination of the scope and contents of prior art.*

Dormoy et al. teach the following reaction:

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(pg. 81, 1<sup>st</sup> column), which is carriedout in a biphasic medium ( $\text{CCl}_4:\text{CH}_3\text{CH}_2\text{OH}$ ).

Carlsen et al. teach the use of ruthenium tetroxide catalyst and periodate ( $\text{IO}_4^-$ ), in aqueous media, for oxidative transformation (pg. 3937, Table 1).

Riley teaches the use of ruthenium catalyst and sodium periodate ( $\text{NaIO}_4$ ), in various solvent systems including water, for oxidative transformation (pg. 1531, Table 1).

Narukawa et al. teach that 1-tert-butoxycarbonyl-4-oxo-L-proline is not largely soluble in water, and is isolated in solid form.

Ascertaining the differences between prior art and instant claims.

The differences between the teaching of Dormoy et al. and the instant claims:

- The oxidation is carried out in biphasic medium in the prior art; the instant claims are drawn to a one-phase aqueous medium
- The oxidation product is allowed to crystallize out.

Resolving the level of ordinary skill in the pertinent art – Prima Facie Case of Obviousness.

The combined teaching of the prior art suggests to one of ordinary skill to practice the instant invention. That is, the teaching of Carlsen et al. and Riley suggests the use of one-phase aqueous systems for the oxidative transformation using ruthenium catalyst in combination with periodate. One of ordinary skill would be motivated to make this modification in order to use solvents that are less toxic, and for simplification of the experimental procedures (for example, eliminate the extraction step). One of ordinary skill would have a reasonable expectation of success in practicing the instant invention.

Furthermore, the teaching of Narukawa et al. shows that the instantly elected product is not largely soluble in aqueous media. Thus, the modification of the prior art reference to practice the instant invention would result in the isolation of the product from the solvent in solid form. The crystallization of compounds as a form of purification is routine to one of ordinary skill. See <http://en.wikipedia.org/wiki/Crystallization>.

It is further noted that optimization of the reaction conditions (eg. temperature) is routine and unpatentable in the absence of unexpected results. The courts have stated that changes in process conditions of an old process does not impart patentability in the absence of unexpected results. In re Boesch, 205 USPQ 215 (1980). In re Aller et al. (CCPA 1955) 220 F2d 454.

In view of the above, the instant claims are *prima facie* obvious over the teaching of the prior art.

***Conclusion***

8. No claims allowed.
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUN JAE Y. LOEWE whose telephone number is (571)272-9074. The examiner can normally be reached on M-F 7:30-5:00 Est.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sun Jae Y. Loewe, Ph.D./  
4-17-2008

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/Kamal Saeed, Ph.D./  
Primary Examiner  
Art Unit 1626